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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,926	07/31/2003	Carlo Riccardi	RICCARDI=1A	7576

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EXAMINER	
LIETO, LOUIS D	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,926	RICCARDI, CARLO	
	Examiner	Art Unit	
	Louis D Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2 and 20, drawn to a nucleic acid construct comprising a GILR cDNA, classified in class 536, subclass 23.1.

II. Claims 3-4,19, drawn to a method of making a GILR transgenic mouse and a GILR transgenic mouse, classified in class 800, subclass 21.

III. Claims 5,6,9 11, 12, and 15, drawn to an isolated cell of the T cell lineage that expresses GILR at an elevated level and a stable cell line established from an isolated cell, classified in class 435, subclass 325.

IV. Claims 7,8, 10, 13, 14, 16, drawn to a method for screening compounds having glucocorticoid –related effects using a stable cell line that expresses GILR, classified in class 435, subclass 6.

V. Claims 3,4,17 and 18, drawn to a GILR transgenic mouse and a method for screening compounds having glucocorticoid –related effects using a GILR transgenic mouse, classified in class 800, subclass 3.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, and II, III, IV, V are patentably distinct. In the instant case the different inventions of group I are to a nucleic acid, while the invention of group II is to a GILR transgenic mouse, and a method of making, the invention of group III is to an isolated cell and a stable cell line, the invention of group IV is to a method for screening compounds using a stable

cell line, while the invention of group V is to a GILR transgenic mouse and a method for screening compounds having glucocorticoid –related effects using a GILR transgenic mouse. The inventions of group I reads on a nucleic acid that is structurally and functionally different from the other groups. The nucleic acids of group I can be used for methods other than the construction of the GLR transgenic mouse of group II and V and the cells of groups III and IV, such as the transfection of T cells for *in vitro* studies, or as a blocking agent for southern blots.

Inventions II, III and V are patentably distinct. In the instant case the different inventions of group II is to a GILR transgenic mouse and a method of making, the invention of group III is to an isolated cell and a stable line, while the invention of group V is to a GILR transgenic mouse and a method for screening compounds. The inventions of group II and V, to a GILR transgenic mouse are different from an isolated cell that expresses GILR and a stable cell line built from the isolated cell. The isolated cell of group III can be made using methods other than the mouse of groups II and groups V, such as *in vitro* transfection. The invention of group III can be used in materially different ways from group II and V, such as the study of GILR related apoptosis *in vitro*. Further, the mouse of group V can be made in a different way than the method of group II, such as nuclear transfer. Finally the mouse of group II can be used in a different method than that of group V, such as the study of GILR related apoptosis *in situ.* The inventions of groups II and III do not require the method of group V.

Inventions II, IV and V are patentably distinct. In the instant case the different inventions of group II is to a GILR transgenic mouse and a method of making, the invention of group IV is to a method for screening compounds having glucocorticoid –related effects using a stable cell line that expresses GILR, while the invention of group V is to a GILR transgenic mouse and a

method for screening compounds. The inventions of group II and V, to a GILR transgenic mouse are different from the method of group IV for screening compounds having glucocorticoid – related effects using a stable cell line that expresses GILR. The stable cell line of group IV can be made using methods other than the mouse of groups II and groups V, such as *in vitro* transfection. Further, the mouse of group V can be made in a different way than the method of group II, such as nuclear transfer. Finally the mouse of group II can be used in a different method than a method for screening compounds having glucocorticoid of group IV or V, such as the study of GILR related apoptosis *in situ.*

Inventions II and V are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)). In the instant case the different inventions of group II is to a GILR transgenic mouse and a method of making, while the invention of group V is to a GILR transgenic mouse and a method of using. The GILR mouse of group II can be used in a materially different way other than the method of V, such as for *in vivo* studies or for *in vitro* studies of primary cells isolated from a GILR transgenic mouse. Further, the mouse of group V can be made in a different way than the method of group II, such as nuclear transfer.

Inventions III, and IV are patentably distinct. In the instant case the different invention of group III is to an isolated cell and a stable cell line, while the invention of group IV is to a method for screening compounds using a stable cell line. The invention of group III can be used

in a materially different fashion than the method of IV, such as the study of GILR related apoptosis *in vitro.*

Furthermore, searching the inventions of groups I-V together would impose a serious search burden. In the instant case, the search of a nucleic acid, an isolated cell that expresses elevated levels of GILR, a transgenic mouse, methods of making a transgenic mouse, methods of using a transgenic mouse and methods of screening compounds are quite different. The nucleic acid is structurally and functionally different from a transgenic mouse and a method of screening compounds. The GILR transgenic mouse could be made and used in multiple different and independent ways, thus, the making and use of the mouse encompass separate searches of the art. Likewise, the isolated cell that expresses elevated levels of GILR could be made and used in multiple different and independent ways. Finally, a method of screening a compound is functionally distinct from the nucleic acid or the transgenic mouse. Thus, the search of groups I-V is not co-extensive. Finally, the inventions of Groups I -V have a separate status in the art as shown by their different sub-classifications. As such, it would be burdensome to search the inventions of groups I-V together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0804. The fax phone number for the

organization where this application or proceeding is assigned is (571)-272-0735. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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PRIMARY EXAMINER